EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC., Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., Defendant.	)	No.: 08-C-1384 Judge Bucklo Magistrate Judge Mason **JURY TRIAL DEMANDED**

DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S RESPONSE TO MORTON GROVE PHARMACEUTICALS, INC.'S FOURTH SET OF INTERROGATORIES

Defendant the National Pediculosis Association, Inc. ("NPA"), by its attorneys, in response to Plaintiff Morton Grove Pharmaceuticals, Inc.'s ("Morton Grove") Fourth Set of Interrogatories, states as follows:

Preliminary Statement

NPA has not completed its investigation, discovery, or preparation for trial in this matter. Accordingly, all responses contained herein are based solely upon such information that is presently available to and known by NPA. NPA expressly reserves the right to supplement or otherwise amend any of its responses or objections to these interrogatories based on the results of NPA's continuing investigation and discovery in this proceeding. NPA further reserves the right to produce evidence of any subsequently discovered facts not yet obtained or known, and to otherwise assert factual and legal contentions as additional facts are ascertained, analyses are made, and legal research is completed.

General Objections

1. NPA objects to Plaintiff's interrogatories, definitions, and instructions to the extent they seek to impose obligations different from, or in addition to, those imposed by the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or any other applicable Local Rules or Standing Orders.

2. NPA objects to Plaintiff's interrogatories, definitions, and instructions to the extent they seek information that is protected from discovery by any applicable privilege or exemption, including the attorney-client privilege and the work-product doctrine. NPA will provide only non-privileged, non-exempt information. To the extent NPA inadvertently discloses any privileged information, such inadvertent disclosure shall not be deemed a waiver of any applicable privilege or exemption.

3. NPA objects to Plaintiff's interrogatories to the extent they seek information not in its possession, custody, or control.

4. NPA objects to Plaintiff's interrogatories to the extent they seek information that can be obtained from public sources or other sources that are more convenient, less burdensome, and/or less expensive.

5. NPA objects to Plaintiff's interrogatories, definitions, and instructions to the extent they assume facts that do not exist or are incorrect. By responding to a particular interrogatory, NPA does not indicate that it agrees, admits, or otherwise acknowledges Morton Grove's characterizations or assumptions of fact or law contained in the interrogatory.

6. NPA objects to Plaintiff's interrogatories, definitions, and instructions to the extent they seek information that is not relevant to any claim or defense in this action. By disclosing information, NPA does not admit the relevance thereof to the subject matter of this

litigation. NPA expressly reserves any and all objections to the relevance and admissibility of any information provided in response to these interrogatories.

7. NPA expressly reserves the right to supplement or modify its objections and responses to Plaintiff's interrogatories based on the results of NPA's continuing investigation and discovery in this proceeding.

8. In order to preserve its objections, NPA objects to Plaintiff's interrogatories to the extent they contain discrete subparts which properly should be separate, individual interrogatories, and to the extent that they exceed the number of interrogatories allowed by the Court.

9. NPA objects to the definition of the terms "NPA," "You," and "Your" in Instruction 3 because they are overly broad and seek information that is neither relevant to this matter nor reasonably calculated to lead to the discovery of admissible evidence. As a non-profit 501(c)(3) organization, NPA has no parents, subsidiaries, investment bankers, or divisions. NPA will define these terms to mean the National Pediculosis Association, its predecessors, affiliates, officers, directors and employees. NPA further objects to the extent these terms are used to seek information that is covered by the attorney-client privilege, work-product doctrine, or other applicable privileges.

10. NPA objects to the instructions with respect to NPA's claims of privilege set forth in Instruction 21 to the extent that they impose obligations in addition to those imposed by Federal Rule of Civil Procedure 26(b)(5). To the extent NPA asserts any claims of privilege, it will do so in accordance with Rule 26(b)(5).

11. Each of the General Objections listed above is to be considered applicable to, and is hereby incorporated by reference into, each of the specific responses below as if fully set forth therein.

Interrogatory Responses

1. Identify all persons who may have personal knowledge of any fact alleged in the Counterclaim (including knowledge as to the truth or falsity of any such fact), and state the general subject matter of the knowledge that may be possessed by each person.

RESPONSE: In addition to and without waiving the General Objections, NPA objects to this interrogatory as overly broad and unduly burdensome because it requires identification of "all persons who may have personal knowledge of any fact alleged in the Counterclaim," which category includes numerous scientists, researchers, physicians, pharmacists, toxicologists, parents, and others who possess knowledge as to the dangers of the chemical lindane and its use in lice and scabies treatments, as well as individuals, such as Morton Grove's counsel, who have acquired personal knowledge by virtue of their participation in this case. NPA further objects to this interrogatory to the extent it seeks to impose an obligation different from or more extensive than those imposed by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the Northern District of Illinois. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: The following persons may have personal knowledge of discoverable information relating to the listed general subject matter relevant to NPA's Counterclaim:

Individual	General subject(s)
Thomas Abrams	Matters concerning the Warning Letter issued to Morton Grove by the FDA in December 2007
Deborah Altschuler	The false or misleading nature of the Morton Grove statements identified in NPA's Counterclaim; the FDA's regulation of lice or scabies treatments containing the chemical lindane; how NPA has been injured or is likely to be injured by Morton Grove's statements;

	competitors to NPA's LiceMeister® Comb
Shayne Gad	The circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim
William Goldberg	The circumstances of the drafting, dissemination, and/or Internet posting of the Morton Grove statements identified in NPA's Counterclaim; Morton Grove's sales and marketing efforts; competitors to Morton Grove's lindane products
Andrew Haffer	Matters concerning the Warning Letter issued to Morton Grove by the FDA in December 2007
Adelaide Hebert	The false or misleading nature of some or all of the Morton Grove statements identified in NPA's Counterclaim; the circumstances of the drafting, dissemination, and Internet posting of her letter identified in the Counterclaim
Ralph Hodosh	The false or misleading nature of some or all of the Morton Grove statements identified in NPA's Counterclaim; the FDA's regulation of lice or scabies treatments containing the chemical lindane; matters concerning the Warning Letter issued to Morton Grove by the FDA in December 2007
Chang Lee	The false or misleading nature of some or all of the Morton Grove statements identified in NPA's Counterclaim; the FDA's regulation of lice or scabies treatments containing the chemical lindane; the circumstances of the drafting and dissemination of his letters identified in the Counterclaim; the circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim; Morton Grove's sales and marketing efforts
Pat McGrath	The circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim; Morton Grove's sales and marketing efforts
Kurt Olofski	Matters concerning the Warning Letter issued to Morton Grove by the FDA in December 2007; Morton Grove's sales and marketing efforts; competitors to Morton Grove's lindane products
Amy S. Paller	The circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim
Don Peckles	The circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim; Morton Grove's sales and marketing efforts; competitors to Morton Grove's lindane products

Tor Shwayder	The false or misleading nature of some or all of the Morton Grove statements identified in NPA's Counterclaim; the circumstances of the drafting, dissemination, and Internet posting of his letter identified in the Counterclaim
Brian Tambi	The circumstances of the drafting, dissemination, and/or Internet posting of some or all of the Morton Grove statements identified in NPA's Counterclaim; Morton Grove's sales and marketing efforts
Other Morton Grove employees and affiliates	During its investigation and discovery, NPA has uncovered information that suggests that current and former employees of Morton Grove or its affiliates who, to date, are unidentified, likely have knowledge of facts relevant to NPA's Counterclaim. These persons include, but are not limited to, Suzanne Gordon, individuals at Closerlook, and current or former employees of Alliant Pharmaceuticals. In particular, because Morton Grove has refused to produce documents concerning the development of www.lindane.com, www.lindanetruth.com, and Closerlook, NPA does not yet know exactly who else may have personal knowledge relevant to NPA's Counterclaim.

NPA further states that its investigation continues.

2. State the basis for the NPA's allegations that the statements attributed to Morton Grove in the Counterclaim are false. For each such statement, please identify all facts upon which you base your allegations(s) of falsity and all persons with knowledge or information regarding your allegation(s) of falsity.

RESPONSE: In addition to and without waiving the General Objections, NPA objects to this interrogatory because "the statements attributed to Morton Grove in the Counterclaim" is vague and ambiguous. NPA interprets this phrase to mean the Morton Grove statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 of NPA's Counterclaim. NPA further objects to this interrogatory as overly broad and unduly burdensome because it requires NPA to identify each and every fact demonstrating the false or misleading nature of the Morton Grove statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 of NPA's Counterclaim. NPA also objects to this interrogatory as overly broad and unduly burdensome because it requires identification of "all persons with knowledge or information regarding your allegation(s) of falsity," which category includes numerous scientists, researchers, physicians,

pharmacists, toxicologists, parents, and others who possess knowledge as to the dangers of the chemical lindane and its use in lice and scabies treatments, as well as individuals, such as Morton Grove's counsel, who have acquired knowledge by virtue of their participation in this case. NPA objects to this interrogatory to the extent it assumes facts not in evidence or contrary to those alleged in NPA's Counterclaim, particularly in that NPA has not alleged that all of the Morton Grove statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 of the Counterclaim are literally false or that all of the facts contained therein are false; rather, NPA has alleged that certain statements are misleading and/or misleading in context, and that some specific facts are false. NPA also objects to this interrogatory because it contains discrete subparts that are properly the subject of separate interrogatories. NPA further objects to this interrogatory to the extent it seeks narrative information more properly obtained through deposition testimony. NPA also objects to this interrogatory to the extent it is duplicative of other interrogatories, such as Interrogatory No. 1 of Morton Grove's Fourth Set of Interrogatories, to which NPA is responding herewith. NPA further objects to this interrogatory to the extent it seeks to impose obligations on NPA that are different from or more extensive than those imposed by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the Northern District of Illinois. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows:

(a) Statement listed in paragraph 48: "The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported."

This statement is misleading, especially given the context of the entire letter in which it appears. Specifically, the statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are.

First, the statement misleadingly suggests that lindane lice or scabies treatments are safe because they have been used for "50+ years" in the United States. This ignores the fact that over those supposed "50+ years," significant changes have occurred in medicine, in science, in the environment, and in how the FDA regulates lindane products. These significant changes mean lindane products are now recognized as: (1) according to the FDA, not the safest option compared to other, newer alternatives; (2) decreasing in effectiveness given the louse's increasing resistance to the chemical lindane, though lindane products never were entirely effective and/or ovicidal; (3) inappropriate or more dangerous to use on children, those with seizure conditions, and pregnant women, among others; (4) more likely to be misused rather than used in accordance with directions; (5) appropriate to be used only as a last resort; (6) banned by the State of California; and (7) not a person's only exposure to the chemical lindane, given its long-term use for agricultural purposes. As a result of these changes in what the FDA, physicians, toxicologists, parents, policymakers, and others know about lindane products, the decision to prescribe and use lindane products today is much different than it was when lindane first arrived on the market. Accordingly, the sheer length of time lindane products have been available does not demonstrate they are safe. Moreover, researchers' and the FDA's knowledge about lindane products has increased over time as further studies are performed and additional data is collected. That increasing body of data as to lindane products has led to increasing FDA restrictions on the products' uses, culminating in the 2003 black box warning. Indeed the FDA's 2003 Public Health Advisory states "Lindane has been on the market since 1951, but was labeled

as second-line therapy in 1995 because there are safer alternative treatments that should be used first." Now, the medication guide accompanying a Lindane Shampoo prescription states: "**[d]o not use Lindane Shampoo . . .** unless it is the only medicine you can use for lice."

Thus, opinions as to safety can change dramatically over time. That is especially true for lindane products, which became available for use at a time when the FDA was much less sophisticated. For this reason, the FDA itself has recognized that its data as to the safety of lindane treatments, particularly when used on children, the elderly, and pregnant women, is lacking. For instance, the National Institutes of Health, in consultation with the FDA and pediatric experts, identified lindane scabies treatments as among a short "List of Drugs for Which Pediatric Studies Are Needed," pursuant to the Best Pharmaceuticals for Children Act. That list "prioritizes certain drugs most in need of study for use by children to ensure their safety and efficacy." Further, the package inserts for Lindane Lotion and Lindane Shampoo state that "[t]here have been no studies of Lindane Shampoo [or Lotion] in the elderly" and "there are no adequate and well-controlled studies of Lindane Shampoo [or Lotion] in pregnant women." Moreover, Morton Grove admits in its own documents that there is a lack of current safety data concerning lindane products. Accordingly, the sheer length of time that lindane products have been available does not demonstrate they are safe. To the contrary, the FDA's actions in increasing its labeling restrictions and the actions of other entities, like the State of California in banning lindane lice or scabies treatments, indicate that with more information and after years of availability, lindane products are considered much less safe than they may have been considered when they first arrived on the U.S. market.

Second, the statement misleadingly implies that lindane products are safe because the same formulations or same lindane products have been available in the United States for "50+

years." To the contrary, different types of lindane products have been sold by different manufacturers over that time period, and some are no longer available. For instance, at one point, manufacturer(s) sold a lindane cream for head lice and a lindane lice spray.

Third, the statement misleadingly implies that lindane products are safe because the FDA's adverse event reporting system is *the* way to determine safety, and that system reveals only "relatively few adverse event reports" related to lindane lice or scabies treatments. In other words, the statement misleadingly suggests that all adverse events are reported and, therefore, that individuals can rely on the "relatively few adverse event reports" associated with lindane products as an indication of their safety. This ignores (1) that an organized adverse event reporting system has not been available for all of the years that lindane products have been available in the United States, and (2) that the adverse event reporting system has serious limitations. The FDA began collecting reports in its spontaneous reporting system database only in 1969. The earliest adverse event report on record with the FDA concerning a lindane product is dated from 1974, and the majority of such reports have been submitted since 1995. In 2002, the FDA's search of the 488 lindane-related reports in its records revealed that 63% had been submitted since 1995. The digital version of the reporting database now contains only adverse event reports received by the FDA since November 1, 1997.

In addition, the ability of even this data to identify the true number of adverse events resulting from use of lindane products is significantly limited. The FDA acknowledges that its adverse event reporting system is based on "a substantial amount of underreporting." The FDA's 2003 Public Health Advisory states, "[r]ates of adverse events cannot be calculated from th[e adverse event] system and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo." Thus, the FDA "estimates that between one and 10% of all

adverse events are reported to the FDA. Other limitations [of the adverse event reporting system] include the variability in the quality and quantity of information reported, as well as the absence of information that does not have a coded field." As the EPA noted in a July 2002 risk assessment memorandum, "the [FDA's adverse event reporting system] database does not include the total number of patients who have been treated, with or without adverse events. Because of this, it is not possible to quantify the percentage of patients who have had adverse events." The FDA similarly provides the following "caveat" regarding its system: "[n]umbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data." Indeed, NPA has received many more reports from parents and others than can be found in the FDA's system. In addition, a voluntary reporting system like the FDA's adverse event reporting database depends on individuals to first make the connection between the use of a lindane product and the resulting adverse event. Such a diagnosis may be difficult because, among other things, (1) parents or others may not mention or doctors and others may not inquire about whether an individual has been treated with a lindane lice or scabies product, and the opportunity for testing or further study is lost; and (2) individuals may be reluctant to admit they have been treated for lice or scabies, given the stigma often associated with such conditions.

Fourth, by stating that "relatively few adverse events have been reported" yet omitting mention of the serious nature of some of those adverse events, which include seizures and deaths, the statement misleadingly suggests that lindane products are safe because there is a supposedly low number of adverse events associated with their use. To the contrary, the serious nature of the adverse events that can accompany lindane use demonstrates that numbers alone do not determine safety, particularly for those patients who are at greater risk for these serious

adverse events. For instance, as to children (those most likely to experience problems with head lice), the FDA's Talk Paper announcing the black box warning states "[s]ince Lindane is absorbed through the skin, and because younger children have more skin surface area per pound of body weight than adults, the amount that is absorbed may result in higher blood levels of Lindane in children than that seen in adults. Animal studies have also shown that younger animals are more susceptible to the neurological side effects seen with Lindane use." As to all patients, the black box itself states: "[s]eizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity."

Fifth, the statement misleadingly implies lindane products are safe because adverse events associated with lindane lice or scabies treatments are so rare that they should be disregarded. To the contrary, in the FDA Talk Paper announcing the black box warning, the FDA stated that the serious risks associated with lindane use were important to consider as part of the decision to prescribe or not prescribe lindane lice or scabies treatments: "Given the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events."

And there are a variety of known serious risks in using lindane lice or scabies treatments. In the FDA's 2003 Public Health Advisory on lindane products, the FDA stated that "[t]he risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from

dizziness to seizures. In postmarketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia." The FDA further warned that there are "concerns of potential increased risk of adverse reactions associated with the use of Lindane products in immuno-compromised patients, such as those with HIV infection, or patients on medications, such as antidepressants, that may increase the chances of having a seizure." The package insert for Lindane Lotion and Lindane Shampoo states: "Central nervous system stimulation ranging from dizziness to seizures, has been reported particularly with use of Lindane Lotion. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported." The package insert for Lindane Shampoo goes on to warn that "[t]he following adverse reactions reflect the additional postmarketing experience of Lindane Shampoo. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria." The patient medication guide for Lindane Shampoo warns that "**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, 'fits' or epilepsy. Seizures and death can happen in people who use Lindane Shampoo too much or too often. Seizures can happen in some people even if they use Lindane Shampoo exactly as directed." The risk of all these serious adverse events increases for those who are inherently vulnerable to lindane products, such as children, the elderly, and pregnant women.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Chang Lee. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(b) Statement listed in paragraph 49: "The great majority of these events, 85% were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use 2 oz. bottles to minimize this risk)."

This statement is misleading, especially given the context of the entire letter in which it appears. Specifically, the statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are.

First, the statement misleadingly implies that lindane products are safe because the FDA's adverse event reporting system is *the* way to determine safety, and that system reveals that "a great majority" of adverse events related to lindane lice or scabies treatments were "non-serious." In other words, the statement misleadingly suggests that all adverse events are reported and, therefore, that individuals can rely on the "great majority" of non-serious events as an indication of the safety of lindane products. This ignores (1) that an organized adverse event reporting system has not been available for all of the years that lindane products have been available in the United States, and (2) that the adverse event reporting system has serious limitations. The FDA began collecting reports in its spontaneous reporting system database only in 1969. The earliest adverse event report on record with the FDA concerning a lindane product

is dated from 1974, and the majority of such reports have been submitted since 1995. In 2002, the FDA's search of the 488 lindane-related reports in its records revealed that 63% had been submitted since 1995. The digital version of the reporting database now contains only adverse event reports received by the FDA since November 1, 1997.

In addition, the ability of even this data to identify the true number of adverse events resulting from use of lindane products is significantly limited. The FDA acknowledges that its adverse event reporting system is based on "a substantial amount of underreporting." The FDA's 2003 Public Health Advisory states, "[r]ates of adverse events cannot be calculated from th[e adverse event] system and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo." Thus, the FDA "estimates that between one and 10% of all adverse events are reported to the FDA. Other limitations [of the adverse event reporting system] include the variability in the quality and quantity of information reported, as well as the absence of information that does not have a coded field." As the EPA noted in a July 2002 risk assessment memorandum, "the [FDA's adverse event reporting system] database does not include the total number of patients who have been treated, with or without adverse events. Because of this, it is not possible to quantify the percentage of patients who have had adverse events." The FDA similarly provides the following "caveat" regarding its system: "[n]umbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data." Indeed, NPA has received many more reports from parents and others than can be found in the FDA's system. In addition, a voluntary reporting system like the FDA's adverse event reporting database depends on individuals to first make the connection between the use of a lindane product and the resulting adverse event. Such a diagnosis may be difficult because,

among other things, (1) parents or others may not mention or doctors and others may not inquire about whether an individual has been treated with a lindane lice or scabies product, and the opportunity for testing or further study is lost; and (2) individuals may be reluctant to admit they have been treated for lice or scabies, given the stigma often associated with such conditions.

Second, the statement misleadingly implies that lindane lice or scabies treatments are dangerous only if misused and safe if used according to instructions. Although lindane products are certainly dangerous if misused, they also can be dangerous even if used according to the FDA's guidelines. Even given the limitations of the FDA's adverse event reporting system described above, as of 2003, at least 20% of the lindane-related adverse events with serious outcomes (hospitalization, disability, or death) resulted from uses according to directions. Twelve uses according to directions resulted in hospitalization, and at least two such "proper" uses resulted in death. The FDA's black box warning on lindane products itself warns that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application used according to directions." Moreover, for those for whom lindane products are to be used only "with caution," such as (according to the black box warning) children, the elderly, and those with skin conditions, even so-called "proper" use may be dangerous. Morton Grove's own documents show that Morton Grove acknowledges that its lindane products have risks even when used according to FDA guidelines.

In addition, by implying that lindane products are dangerous only if misused, the statement misleadingly oversimplifies the practical realities of how people use such products when confronting a lice infestation or a scabies outbreak, and it blames individuals for dangers that are inherent in the use of lindane products. Reports received by Morton Grove itself indicate

that individuals frequently misuse lindane products. NPA's data and communications with parents and others who have used lindane products indicates that "normal" use of lindane products is misuse – that when faced with the need to treat lice or scabies, people may overtreat or ignore instructions, if they are even aware of the instructions. In particular, people may overtreat because they (inaccurately) believe lindane products to be 100% effective and assume they must not have applied enough if the product fails. Further, despite the FDA's mandated labeling and package inserts for lindane products, those dealing with lice or scabies may not always be adequately informed of the directions for use, also increasing the potential for overtreatment or other misuse. Also, in the FDA's 1996 Talk Paper explaining that the FDA had made lindane products options only as a last resort, "[t]he reasons for the products' misuse may be connected with pruritus – itching that continues after successful treatment – due to the residual inflammation in the skin. When the treated children continue to scratch, some parents may continue to medicate beyond the recommended procedure. In other cases, parents may be inclined to overuse the product in their zeal to treat children as quickly as possible. This increases the amount of lindane to which children are exposed and raises the likelihood for adverse reactions to occur."

Third, this statement misleadingly implies that lindane products are safe because the manufacturer has decided to package them in 2-ounce bottles and it is impossible to misuse them when they are dispensed in 2-ounce bottles. To the contrary, the FDA, rather than Morton Grove, made the decision to establish a requirement that limits the size of lindane bottles to two ounces at most. Moreover, that lindane products are dispensed in 2-ounce bottles does not mean two ounces is a proper dose. Specifically, the labeling for Lindane Shampoo and Lindane Lotion indicate that some product likely will be leftover after treatment; both inserts instruct users to

"[c]lose the bottle with the leftover [lindane product] and immediately throw it away in a trash can out of the reach of children." For Lindane Lotion, that labeling further states: "One ounce is sufficient for an average adult. Do not prescribe more than 2 ounces for larger adults." For Lindane Shampoo, it states: "Most patients will require only 1 ounce of Lindane Shampoo. Based on the length and density of hair, some patients may require 2 ounces of Lindane Shampoo." Further, the medication guide for Lindane Lotion instructs: "Put a very thin layer of the Lindane Lotion on your skin from the neck down. You may have some Lindane Lotion left in the bottle." Similarly, the Lindane Shampoo medication guide instructs: "Use just enough Lindane Shampoo on your dry hair to wet your hair and scalp. . . . Close the bottle with the leftover Lindane Shampoo and throw it away in a trash can **out of the reach of children.**"

In addition, that lindane products are dispensed in 2-ounce bottles does not mean that two ounces cannot be harmful. Indeed, two ounces of a lindane lice or scabies treatment, if ingested, could be fatal. Further, two ounces of a lindane product used on someone for whom the product is contraindicated also could cause serious side effects.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Chang Lee. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(c) Statement listed in paragraph 51: "From 1951 through 2002, only 3 deaths confirmed to be related to lindane medications were reported through the FDA AERS [Adverse

Event Reporting System] database. In each instance, these medications were misused (see claims #1 and #3)."

This statement is misleading, especially given the context of the entire letter in which it appears. Specifically, this statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are.

First, the statement misleadingly implies that lindane products are safe because the FDA's adverse event reporting system is *the* way to determine safety, and that system reveals "only 3 deaths confirmed to be related" to lindane lice or scabies treatments. In other words, the statement misleadingly suggests that all adverse events are reported and, therefore, the fact that "only 3 deaths" have been reported demonstrates the safety of lindane products. This ignores (1) that an organized adverse event reporting system has not been available for all of the years that lindane products have been available in the United States, and (2) that the adverse event reporting system has serious limitations. The FDA began collecting reports in its spontaneous reporting system database only in 1969. The earliest adverse event report on record with the FDA concerning a lindane product is dated from 1974, and the majority of such reports have been submitted since 1995. In 2002, the FDA's search of the 488 lindane-related reports in its records revealed that 63% had been submitted since 1995. The digital version of the reporting database now contains only adverse event reports received by the FDA since November 1, 1997.

In addition, the ability of even this data to identify the true number of adverse events resulting from use of lindane products is significantly limited. The FDA acknowledges that its adverse event reporting system is based on "a substantial amount of underreporting." The FDA's 2003 Public Health Advisory states, "[r]ates of adverse events cannot be calculated from th[e adverse event] system and underreporting is presumed, especially for older products like

Lindane Lotion and Shampoo." Thus, the FDA "estimates that between one and 10% of all adverse events are reported to the FDA. Other limitations [of the adverse event reporting system] include the variability in the quality and quantity of information reported, as well as the absence of information that does not have a coded field." As the EPA noted in a July 2002 risk assessment memorandum, "the [FDA's adverse event reporting system] database does not include the total number of patients who have been treated, with or without adverse events. Because of this, it is not possible to quantify the percentage of patients who have had adverse events." The FDA similarly provides the following "caveat" regarding its system: "[n]umbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data." Indeed, NPA has received many more reports from parents and others than can be found in the FDA's system. In addition, a voluntary reporting system like the FDA's adverse event reporting database depends on individuals to first make the connection between the use of a lindane product and the resulting adverse event. Such a diagnosis may be difficult because, among other things, (1) parents or others may not mention or doctors and others may not inquire about whether an individual has been treated with a lindane lice or scabies product, and the opportunity for testing or further study is lost; and (2) individuals may be reluctant to admit they have been treated for lice or scabies, given the stigma often associated with such conditions.

Second, the statement misleadingly implies that lindane lice or scabies treatments are dangerous only if misused and safe if used according to instructions. Although lindane products are certainly dangerous if misused, they also can be dangerous even if used according to the FDA's guidelines. Even given the limitations of the FDA's adverse event reporting system described above, as of 2003, at least 20% of the lindane-related adverse events with serious

outcomes (hospitalization, disability, or death) resulted from uses according to directions. Twelve uses according to directions resulted in hospitalization, and at least two such "proper" uses resulted in death. The FDA's black box warning on lindane products itself warns that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application used according to directions." The FDA's 2003 Public Health Advisory on lindane products warns that "[t]he risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In postmarketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia." The package insert for Lindane Lotion and Lindane Shampoo warns that "[t]here have been cases of adverse events reported for Lindane Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred. In approximately 20% of these cases, the shampoo and lotion were reported to have been used according to the labeled directions." The patient medication guide for Lindane Shampoo further states that "**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, 'fits' or epilepsy. Seizures and death can happen in people who use Lindane Shampoo too much or too often. Seizures can happen in some people even if they use Lindane Shampoo exactly as directed." Moreover, for those for whom lindane products are to be used only "with caution," such as (according to the black box warning) children, the elderly, and those with skin conditions, even so-called "proper" use may

be dangerous. Morton Grove's own documents show that Morton Grove acknowledges that its lindane products have risks even when used according to FDA guidelines.

In addition, by implying that lindane products are dangerous only if misused, the statement misleadingly oversimplifies the practical realities of how people use such products when confronting a lice infestation or a scabies outbreak, and it blames individuals for dangers that are inherent in the use of lindane products. Reports received by Morton Grove itself indicate that individuals frequently misuse lindane products. NPA's data and communications with parents and others who have used lindane products indicates that "normal" use of lindane products is misuse – that when faced with the need to treat lice or scabies, people may overtreat or ignore instructions, if they are even aware of the instructions. In particular, people may overtreat because they (inaccurately) believe lindane products to be 100% effective and assume they must not have applied enough if the product fails. Further, despite the FDA's mandated labeling and package inserts for lindane products, those dealing with lice or scabies may not always be adequately informed of the directions for use, also increasing the potential for overtreatment or other misuse. Also, in the FDA's 1996 Talk Paper explaining that the FDA had made lindane products options only as a last resort, "[t]he reasons for the products' misuse may be connected with pruritus – itching that continues after successful treatment – due to the residual inflammation in the skin. When the treated children continue to scratch, some parents may continue to medicate beyond the recommended procedure. In other cases, parents may be inclined to overuse the product in their zeal to treat children as quickly as possible. This increases the amount of lindane to which children are exposed and raises the likelihood for adverse reactions to occur."

Third, the statement misleadingly implies that lindane lice or scabies treatments are safe because "only 3" deaths have been "confirmed" to be related to these products. This ignores the fact that 17 deaths have been "associated with" the use of lindane products, as the FDA stated in its 2003 Public Health Advisory, and thus understates the risks of lindane products. Further, this statistic suffers from the same limitations as all data derived from the FDA's adverse event reporting system, described above.

Fourth, the statement misleadingly suggests that lindane lice or scabies treatments are safe because serious adverse events like death are so rare that the risks of such serious events should be disregarded. Yet it is the presence of those other serious risks – such as seizures – that prompted the FDA's black box warning on lindane products. In the FDA Talk Paper announcing the black box warning, the FDA stated that the serious risks associated with lindane use were important to consider as part of the decision to prescribe or not prescribe lindane lice or scabies treatments: "Given the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events."

And there are a variety of known serious risks in using lindane lice or scabies treatments. In the FDA's 2003 Public Health Advisory on lindane products, the FDA stated that "[t]he risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In postmarketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia." The FDA further warned that there are "concerns

of potential increased risk of adverse reactions associated with the use of Lindane products in immuno-compromised patients, such as those with HIV infection, or patients on medications, such as antidepressants, that may increase the chances of having a seizure." The package insert for Lindane Lotion and Lindane Shampoo states: "Central nervous system stimulation ranging from dizziness to seizures, has been reported particularly with use of Lindane Lotion. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported." The package insert for Lindane Shampoo goes on to warn that "[t]he following adverse reactions reflect the additional postmarketing experience of Lindane Shampoo. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria." The patient medication guide for Lindane Shampoo warns that "**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, 'fits' or epilepsy. Seizures and death can happen in people who use Lindane Shampoo too much or too often. Seizures can happen in some people even if they use Lindane Shampoo exactly as directed." The risk of all these serious adverse events increases for those who an inherently vulnerable to lindane products, such as children, the elderly, and pregnant women.

Fifth, by omitting mention of any of the other serious side effects deriving from the use of lindane products, the statement misleadingly implies that these products are safe because the risk of death is small, and there are no other serious side effects to be concerned about. As explained above, to the contrary, there are risks of other serious adverse events – particularly seizures – that are cause for concern regardless of whether the lindane treatment is misused or

used in accordance with directions. In addition, for certain patients, the risk of certain serious adverse events is a greater cause for concern.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Chang Lee. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(d) Statements listed in paragraphs 48, 49, and 51:

For the reasons explained above, the statements listed in paragraphs 48, 49, and 51 of NPA's Counterclaim, and all found in the same Morton Grove letters, create the overall misleading impression that (1) lindane lice or scabies treatments are safer than they really are; (2) that such products are safe for all patients; and (3) that such products are dangerous only if misused and safe if used according to instructions.

(e) Statement listed in paragraph 63: "The FDA has quantified serious adverse events (AEs) as rare when lindane pediculicides are used properly—an assessment that is based on more than 50 years of prescription use in tens of millions of patients. The fact is that lindane pediculicides are generally safe and well tolerated. The most common side effects are nonserious reactions of the skin, such as itching and dryness."

This statement is misleading, especially given the context of the entire letter in which it appears. Specifically, the statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are and are safer for all patients than they really are.

First, the statement misleadingly suggests that lindane lice or scabies treatments are safe because they have been used for "more than 50 years" in the United States. This ignores the fact that over those supposed "50+ years," significant changes have occurred in medicine, in science, in the environment, and in how the FDA regulates lindane products. These significant changes mean lindane products are now recognized as: (1) according to the FDA, not the safest option compared to other, newer alternatives; (2) decreasing in effectiveness given the louse's increasing resistance to the chemical lindane, though lindane products never were entirely effective and/or ovicidal; (3) inappropriate or more dangerous to use on children, those with seizure conditions, and pregnant women, among others; (4) more likely to be misused rather than used in accordance with directions; (5) appropriate to be used only as a last resort; (6) banned by the State of California; and (7) not a person's only exposure to the chemical lindane, given its long-term use as for agricultural purposes. As a result of these changes in what the FDA, physicians, toxicologists, parents, policymakers, and others know about lindane products, the decision to prescribe and use lindane products today is much different than it was when lindane first arrived on the market. Accordingly, the sheer length of time lindane products have been available does not demonstrate they are safe. Moreover, researchers' and the FDA's knowledge about lindane products has increased over time as further studies are performed and additional data is collected. That increasing body of data as to lindane products has led to increasing FDA restrictions on the products' uses, culminating in the 2003 black box warning. Indeed the FDA's 2003 Public Health Advisory states "Lindane has been on the market since 1951, but was labeled as second-line therapy in 1995 because there are safer alternative treatments that should be used first." Now, the medication guide accompanying a Lindane Shampoo prescription states: "**[d]o not use Lindane Shampoo . . .** unless it is the only medicine you can use for lice."

Thus, opinions as to safety can change dramatically over time. That is especially true for lindane products, which became available for use at a time when the FDA was much less sophisticated. For this reason, the FDA itself has recognized that its data as to the safety of lindane treatments, particularly when used on children, the elderly, and pregnant women, is lacking. For instance, the National Institutes of Health, in consultation with the FDA and pediatric experts, identified lindane scabies treatments as among a short "List of Drugs for Which Pediatric Studies Are Needed," pursuant to the Best Pharmaceuticals for Children Act. That list "prioritizes certain drugs most in need of study for use by children to ensure their safety and efficacy." Further, the package inserts for Lindane Lotion and Lindane Shampoo state that "[t]here have been no studies of Lindane Shampoo [or Lotion] in the elderly" and "there are no adequate and well-controlled studies of Lindane Shampoo [or Lotion] in pregnant women." Moreover, Morton Grove admits in its own documents that there is a lack of current safety data concerning lindane products. Accordingly, the sheer length of time that lindane products have been available does not demonstrate they are safe. To the contrary, the FDA's actions in increasing its labeling restrictions and the actions of other entities, like the State of California in banning lindane lice or scabies treatments, indicate that with more information and after years of availability, lindane products are considered much less safe than they may have been considered when they first arrived on the U.S. market.

Second, the statement misleadingly implies that lindane products are safe because the same formulations or same lindane products have been available in the United States for "more than 50 years." To the contrary, different types of lindane products have been sold by different manufacturers over that time period. For instance, at one point, manufacturer(s) sold a lindane cream for head lice and a lindane lice spray.

Third, the statement misleadingly suggests that lindane lice or scabies treatments are "generally safe and well tolerated" for all patients. To the contrary, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity" and that the products are "contraindicated in premature infants and individuals with known uncontrolled seizure disorders." The package insert accompanying Lindane Shampoo further states: "Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane. Lindane Shampoo is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug. Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components." The Centers for Disease Control and Prevention agrees lindane products are not safe for all persons: "Lindane should not be used to treat premature infants, persons with a seizure disorder, women who are pregnant or breast-feeding, persons who have very irritated skin or sores where the lindane will be applied, infants, children, the elderly, and persons who weigh less than 110 pounds."

As to children, the FDA's labeling information for Lindane Shampoo and Lindane Lotion states: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." The FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated that younger

animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." As to children and the elderly, the FDA's 2003 Public Health Advisory warns: Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes."

As to those with other health conditions or taking other medications, the advisory further warns: "Patients who have conditions, such as HIV infection, or take certain medications that may lower the seizure threshold should be prescribed Lindane with caution. They may be at greater risk for serious adverse events." The package insert for Lindane Shampoo states: "Careful consideration should be given before prescribing Lindane Shampoo to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold."

As to pregnant women, the labeling information for lindane products itself warns that pregnant women, and their fetuses, are at risk both when the mother is the person applying a lindane product and when the mother is being treated with a lindane product. The package insert for Lindane Shampoo warns that "[i]f the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible" and "[i]f the patient could be pregnant, other treatments may be preferable." That insert further states:

> Lindane Shampoo should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Shampoo in pregnant women. There are no known maternal or fetal health risks described if lice are not treated, but risk of transmission of the lice to other household members is an additional consideration when deciding whether to use lice treatments. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures during pregnancy to Lindane Lotion. The relationship of the maternal exposures to the fetal outcome is unknown.
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> Animal data suggest that lindane may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair covered areas is expected to be lower than that from Lindane Lotion that covers the entire body surface area.

It also warns: "[i]f you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others."

Similarly, infants are also at risk when a mother uses lindane while breastfeeding. The package inserts for Lindane Shampoo and Lotion state: "Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use." The Lindane Shampoo insert further warns patients "**[d]o not use Lindane Shampoo . . .** while you are breast-feeding. Lindane Shampoo can get in your milk and

may be fed to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo."

Fourth, the statement misleadingly implies lindane lice or scabies treatments are safe because the most a person has to be concerned about are "nonserious reactions of the skin, such as itching and dryness." Yet it is the presence of serious risks – such as seizures and death – that prompted the FDA's black box warning on lindane products. In the FDA Talk Paper announcing the black box warning, the FDA stated that the serious risks associated with lindane use were important to consider as part of the decision to prescribe or not prescribe lindane lice or scabies treatments: "Given the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events." And there are a variety of known serious risks in using lindane lice or scabies treatments. In the FDA's 2003 Public Health Advisory on lindane products, the FDA stated that "[t]he risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In postmarketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia." The FDA further warned that there are "concerns of potential increased risk of adverse reactions associated with the use of Lindane products in immuno-compromised patients, such as those with HIV infection, or patients on medications, such as

antidepressants, that may increase the chances of having a seizure." The package insert for Lindane Lotion and Lindane Shampoo states: "Central nervous system stimulation ranging from dizziness to seizures, has been reported particularly with use of Lindane Lotion. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported." The package insert for Lindane Shampoo goes on to warn that "[t]he following adverse reactions reflect the additional postmarketing experience of Lindane Shampoo. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria." The patient medication guide for Lindane Shampoo warns that "**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, 'fits' or epilepsy. Seizures and death can happen in people who use Lindane Shampoo too much or too often. Seizures can happen in some people even if they use Lindane Shampoo exactly as directed."

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and the unknown Morton Grove author of this statement. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(f) Statement listed in paragraph 68: "Lindane is safe, effective, it is not toxic if used as directed" and "[m]y training in both pediatrics and dermatology allows me to judge this issue."

This statement is misleading, especially given the context of the entire letter in which it appears and the entirety of the websites on which it is posted. Specifically, this statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are and that such products are appropriately or safely used on children, who are the patients of pediatric physicians.

First, the statement misleadingly implies that lindane lice or scabies treatments are dangerous only if misused and safe if used according to instructions. Although lindane products are certainly dangerous if misused, they also can be dangerous even if used according to the FDA's guidelines. Even given the limitations of the FDA's adverse event reporting system described above, as of 2003, at least 20% of the lindane-related adverse events with serious outcomes (hospitalization, disability, or death) resulted from uses according to directions. Twelve uses according to directions resulted in hospitalization, and at least two such "proper" uses resulted in death. The FDA's black box warning on lindane products itself warns that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application used according to directions." The FDA's 2003 Public Health Advisory on lindane products warns that "[t]he risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In postmarketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia." The package insert for Lindane Lotion and Lindane Shampoo warns that "[t]here have been cases of adverse events reported for Lindane

Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred. In approximately 20% of these cases, the shampoo and lotion were reported to have been used according to the labeled directions." The patient medication guide for Lindane Shampoo further states that "**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, 'fits' or epilepsy. Seizures and death can happen in people who use Lindane Shampoo too much or too often. Seizures can happen in some people even if they use Lindane Shampoo exactly as directed." Moreover, for those for whom lindane products are to be used only "with caution," such as (according to the black box warning) children, the elderly, and those with skin conditions, even so-called "proper" use may be dangerous. Morton Grove's own documents show that Morton Grove acknowledges that its lindane products have risks even when used according to FDA guidelines.

In addition, by implying that lindane products are dangerous only if misused, the statement misleadingly oversimplifies the practical realities of how people use such products when confronting a lice infestation or a scabies outbreak, and it blames individuals for dangers that are inherent in the use of lindane products. Reports received by Morton Grove itself indicate that individuals frequently misuse lindane products. NPA's data and communications with parents and others who have used lindane products indicates that "normal" use of lindane products is misuse – that when faced with the need to treat lice or scabies, people may overtreat or ignore instructions, if they are even aware of the instructions. In particular, people may overtreat because they (inaccurately) believe lindane products to be 100% effective and assume they must not have applied enough if the product fails. Further, despite the FDA's mandated labeling and package inserts for lindane products, those dealing with lice or scabies may not

always be adequately informed of the directions for use, also increasing the potential for overtreatment or other misuse. Also, in the FDA's 1996 Talk Paper explaining that the FDA had made lindane products options only as a last resort, "[t]he reasons for the products' misuse may be connected with pruritus – itching that continues after successful treatment – due to the residual inflammation in the skin. When the treated children continue to scratch, some parents may continue to medicate beyond the recommended procedure. In other cases, parents may be inclined to overuse the product in their zeal to treat children as quickly as possible. This increases the amount of lindane to which children are exposed and raises the likelihood for adverse reactions to occur."

Second, the statement misleadingly suggests that lindane lice or scabies treatments are "safe" for all patients. To the contrary, no treatment is safe for all patients. As to lindane products, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity" and that the products are "contraindicated in premature infants and individuals with known uncontrolled seizure disorders." The package insert accompanying Lindane Shampoo further states: "Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane. Lindane Shampoo is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug. Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components." The Centers for

Disease Control and Prevention agrees lindane products are not safe for all persons: "Lindane should not be used to treat premature infants, persons with a seizure disorder, women who are pregnant or breast-feeding, persons who have very irritated skin or sores where the lindane will be applied, infants, children, the elderly, and persons who weigh less than 110 pounds."

As to children, the FDA's labeling information for Lindane Shampoo and Lindane Lotion states: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." The FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." As to children and the elderly, the FDA's 2003 Public Health Advisory warns: "Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes."

As to those with other health conditions or taking other medications, the advisory further warns: "Patients who have conditions, such as HIV infection, or take certain medications that may lower the seizure threshold should be prescribed Lindane with caution. They may be at greater risk for serious adverse events." The package insert for Lindane Shampoo states: "Careful consideration should be given before prescribing Lindane Shampoo to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or

a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold."

As to pregnant women, the labeling information for lindane products itself warns that pregnant women, and their fetuses, are at risk both when the mother is the person applying a lindane product and when the mother is being treated with a lindane product. The package insert for Lindane Shampoo warns that "[i]f the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible" and "[i]f the patient could be pregnant, other treatments may be preferable." That insert further states:

> Lindane Shampoo should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Shampoo in pregnant women. There are no known maternal or fetal health risks described if lice are not treated, but risk of transmission of the lice to other household members is an additional consideration when deciding whether to use lice treatments. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures during pregnancy to Lindane Lotion. The relationship of the maternal exposures to the fetal outcome is unknown.
>
> Animal data suggest that lindane may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair covered areas is expected to be lower than that from Lindane Lotion that covers the entire body surface area.

It also warns: "[i]f you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others."

Similarly, infants are also at risk when a mother uses lindane while breastfeeding. The package inserts for Lindane Shampoo and Lotion state: "Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use." The Lindane Shampoo insert further warns patients "**[d]o not use Lindane Shampoo . . .** while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo."

Third, this statement misleadingly implies that lindane lice or scabies treatments are appropriately and freely used on children, who are the patients of pediatric physicians. To the contrary, FDA guidelines state that lindane products are to be used "with caution" on children, and not at all on premature infants. Further dangers connected to the use of lindane products on children are described above.

Fourth, this statement misleadingly at best and falsely at worst suggests that lindane lice or scabies treatments are safe because they are "not toxic." To the contrary, lindane products carry risks of neurotoxicity particularly when misused but also when used as directed, as the black box warnings' "Neurologic Toxicity" section indicates. Moreover, lindane products *are*

toxic by their very nature: the chemical lindane is a pesticide, a poison, and a known neurotoxin. The EPA has stated that "Lindane is quite toxic to humans" and "Lindane is a moderately toxic compound in EPA toxicity class II." As even Morton Grove admits, there are three deaths confirmed to be attributed to use of lindane products; seventeen more are associated with use of lindane products. The American Heritage Dictionary defines "toxic" as "capable of causing injury or death"; Webster's Dictionary defines "toxic" as "containing or being poisonous material especially when capable of causing death or serious debilitation." Further, to a lay person reading this statement on www.lindane.com or www.lindanetruth.com, the phrase "not toxic" implies "no danger," particularly because of the established perception that consumer products labeled as "not toxic" have a high level of safety.

Fifth, this statement and its placement on www.lindane.com and www.lindanetruth.com misleadingly or falsely suggest that lindane lice or scabies treatments are safe because an independent expert on par with the FDA believes them to be safe. This statement is posted on a portion of www.lindane.com and www.lindanetruth.com titled "Medical and Scientific Opinions," which consists of links to documents from several sources, including the FDA and the EPA. The placement of Dr. Shwayder's letter next to these independent materials falsely implies that he is an independent expert on lindane products. To the contrary, NPA has uncovered evidence that suggests Dr. Shwayder has been a paid consultant for defendants in actions involving lindane products; this consulting work compromises Dr. Shwayder's objectivity. In addition, labeling his statements a "Medical and Scientific Opinion[]" on par with statements made by the FDA and EPA misleadingly suggests that his statements about lindane products should be given the same weight as statements made by the FDA and EPA.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Dr. Tor Shwayder. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(g) Statement listed in paragraph 69: "The University of Michigan Medical School taught the use of Lindane for scabies and lice during my training there. The same was true of my pediatric residency at U of M."

NPA lacks information as to whether Dr. Shwayder was educated at the University of Michigan Medical School. However, even if that fact were true, this statement is misleading, especially given the context of the entire letter in which it appears and the entirety of the websites on which it is posted. Specifically, this statement misleadingly suggests that lindane lice or scabies treatments are appropriately used on children, who are the patients of pediatric physicians; that such treatments are safe because reputable schools such as the University of Michigan recommend or endorse such treatments without a second thought; and that such treatments are safe because recommendations and scientific or medical views on their safety have not changed since Dr. Shwayder graduated from medical school.

First, this statement misleadingly implies that lindane lice or scabies treatments are appropriately, safely, and freely used on children, who are the most likely to have problems with head lice. To the contrary, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs

(50 kg) as they may be at risk of serious neurotoxicity" and that the products are "contraindicated in premature infants and individuals with known uncontrolled seizure disorders." The package insert accompanying Lindane Shampoo states: "Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane." The insert further warns: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." Moreover, the FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." That Advisory further warns: "Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes." The FDA Talk Paper announcing the black box states: "The new boxed warning also states that Lindane Lotion and Lindane Shampoo are to be used with caution in patients who weigh less that approximately 110 pounds (50 kilograms). These products are not recommended for use in infants, and are contraindicated in premature infants. These warnings are based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients." The Centers

for Disease Control and Prevention states that lindane products "should not be used to treat" children for head lice.

Second, this statement misleadingly implies that lindane lice or scabies treatments are safe because they are readily prescribed, are the preferred treatment option, or are the typical or standard treatment for lice or scabies. To the contrary, since 1995, the FDA has considered lindane lice or scabies treatments as options only as a last resort, which means they are to be used, if at all, only when other treatment options have failed or when the patient cannot tolerate a safer treatment, such as because of an allergy. The medication guide for Lindane Shampoo advises individuals "[d]o not use Lindane Shampoo unless: You have lice and another medicine did not work for you, or [y]ou cannot use other, safer medicines to treat your lice." It further states: **"[d]o not use Lindane Shampoo . . .** unless it is the only medicine you can use for lice." Such statements acknowledge that safer options exist. Further, as the black box warning indicates, for some individuals (premature infants and those with uncontrolled seizure disorders), lindane products are not to be used at all.

Third, this statement misleadingly implies that lindane lice or scabies treatments are safe because they are endorsed or recommended by a reputable school such as the University of Michigan. However, in its "Head Lice Manual," the State of Michigan itself states that it "**does not recommend using Lindane.**" Similarly, the Michigan Department of Community Health's Scabies Prevention and Control Manual states: "**The Michigan Department of Community Health does not recommend the use of Lindane to treat scabies patients.** . . . Lindane is no longer recommended for use due to recent concerns of drug resistance and severe adverse reactions, including death." In addition, a variety of health professional organizations in Michigan have publicly supported a phase-out of lindane lice and scabies products in that state.

Fourth, this statement misleadingly implies that lindane lice or scabies treatments are safe because recommendations and scientific or medical views on their safety have not changed since Dr. Shwayder graduated from medical school. To the contrary, recommendations as to the use of lindane products have changed over time. Specifically, among other things, FDA guidelines have become more restrictive in light of increased data as to the risks and high potential for misuse of such products, and the State of California has banned all lindane products.

Fifth, this statement and its placement on www.lindane.com and www.lindanetruth.com misleadingly or falsely suggest that lindane lice or scabies treatments are safe because an independent expert on par with the FDA believes them to be safe. This statement is posted on a portion of www.lindane.com and www.lindanetruth.com titled "Medical and Scientific Opinions," which consists of links to documents from several sources, including the FDA and the EPA. The placement of Dr. Shwayder's letter next to these independent materials falsely implies that he is an independent expert on lindane products. To the contrary, NPA has uncovered evidence that suggests Dr. Shwayder has been a paid consultant for defendants in actions involving lindane products; this consulting work compromises Dr. Shwayder's objectivity. In addition, labeling his statements a "Medical and Scientific Opinion[]" on par with statements made by the FDA and EPA misleadingly suggests that his statements about lindane products should be given the same weight as statements made by the FDA and EPA.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Dr. Tor Shwayder. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as

good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(h) Statement listed in paragraph 70: "I have even used it on myself, my children and my pregnant wife." And: "[T]hat fetus exposed to Lindane when my wife used it, what happened to her? She just finished her freshman year at Harvard with stellar grades in high-level courses. Don't let these alarmist anti-Lindane advocates scare you into thinking Lindane is a dreadful neurotoxin. It just isn't so."

NPA has no information regarding whether Dr. Shwayder, his children, and his pregnant wife have used lindane or whether his daughter attends Harvard. However, this statement is misleading, especially given the context of the entire letter in which it appears and the entirety of the websites on which it is posted, and false in part. Specifically, this statement misleadingly suggests that lindane lice or scabies treatments are safer than they really are and that they are appropriately used on pregnant mothers and children. In addition, this statement is false to the extent it claims the chemical lindane is not a neurotoxin.

First, this statement misleadingly suggests that lindane lice or scabies treatments are safe to be used on pregnant women, and that there are no risks for either the pregnant mother or the exposed fetus. To the contrary, the labeling information for lindane products itself warns that pregnant women, and their fetuses, are at risk both when the mother is the person applying a lindane product and when the mother is being treated with a lindane product. The package insert for Lindane Shampoo warns that "[i]f the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible" and "[i]f the patient could be pregnant, other treatments may be preferable." That insert further states:

> Lindane Shampoo should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies

> of Lindane Shampoo in pregnant women. There are no known maternal or fetal health risks described if lice are not treated, but risk of transmission of the lice to other household members is an additional consideration when deciding whether to use lice treatments. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures during pregnancy to Lindane Lotion. The relationship of the maternal exposures to the fetal outcome is unknown.
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> Animal data suggest that lindane may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair covered areas is expected to be lower than that from Lindane Lotion that covers the entire body surface area.

It also warns: "[i]f you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others." The Centers for Disease Control and Prevention states that lindane products "should not be used to treat" women who are pregnant or breast-feeding for head lice.

Similarly, infants are also at risk when a mother uses lindane while breastfeeding. The package inserts for Lindane Shampoo and Lotion state: "Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use." The Lindane Shampoo insert further warns patients "**[d]o not use**

Lindane Shampoo . . . while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo."

Second, this statement misleadingly implies that lindane products are appropriately or safely used on children, who are the most likely to have problems with head lice. To the contrary, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity." Further, the FDA's labeling information for Lindane Shampoo and Lindane Lotion states: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." The FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." As to children and the elderly, the FDA's 2003 Public Health Advisory warns: "Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes."

The Centers for Disease Control and Prevention states that lindane products "should not be used to treat" children for head lice.

Third, this statement falsely states that the chemical lindane is not a neurotoxin. To the contrary, the chemical lindane is a documented neurotoxin. In its toxicology chapter for lindane in connection with the reregistration eligibility decision that led to the withdrawal of lindane for use as an agricultural pesticide, the EPA concluded: "Lindane is a neurotoxicant. In acute, subchronic and developmental neurotoxicity studies, it was found to cause neurotoxic effects including tremors, convulsions, decreased motor activity, increased forelimb grip strength, hypersensitivity to touch, hunched posture and decreased motor activity habituation." The EPA has further stated: "Lindane primarily affects the nervous system causing neurotoxic effects." The EPA also has acknowledged: "In fact, California banned the pharmaceutical uses of lindane due to concerns about water contamination and acute neurotoxicity concerns from direct application." The FDA's black box warning for lindane products acknowledges the potential for lindane lice and scabies treatments to cause "neurologic toxicity," and its 2003 Public Health Advisory states: "The risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In post-marketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia."

Fourth, this statement and its placement on www.lindane.com and www.lindanetruth.com misleadingly or falsely suggest that lindane lice or scabies treatments are safe because an independent expert on par with the FDA believes them to be safe. This

statement is posted on a portion of www.lindane.com and www.lindanetruth.com titled "Medical and Scientific Opinions," which consists of links to documents from several sources, including the FDA and the EPA. The placement of Dr. Shwayder's letter next to these independent materials falsely implies that he is an independent expert on lindane products. To the contrary, NPA has uncovered evidence that suggests Dr. Shwayder has been a paid consultant for defendants in actions involving lindane products; this consulting work compromises Dr. Shwayder's objectivity. In addition, labeling his statements a "Medical and Scientific Opinion[]" on par with statements made by the FDA and EPA misleadingly suggests that his statements about lindane products should be given the same weight as statements made by the FDA and EPA.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Dr. Tor Shwayder. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(i) Statements listed in paragraphs 68, 69, and 70:

For the reasons explained above, the statements listed in paragraphs 68, 69, and 70 of NPA's Counterclaim, and all found in the same letter posted on www.lindane.com and www.lindanetruth.com, create the overall misleading impression that (1) lindane lice or scabies treatments are safer than they really are; (2) that such products are safe for all patients, including pregnant women and children; (3) that such products are dangerous only if misused and safe if

used according to instructions; and (4) that independent experts on par with the FDA and EPA believe lindane products are safe.

(j) Statement listed in paragraph 73: "I have enclosed some photographs of a two-year-old girl who was previously treated for scabies with oral Ivermectin, one of the most potent medications on the market. The patient failed Ivermectin therapy and was subsequently treated successfully with Lindane."

This statement is misleading, especially given the context of the entire letter in which it appears and the entirety of the websites on which it is posted. Specifically, this statement misleadingly suggests that lindane lice or scabies treatments are safe for use on children and that they are more effective than other treatments.

First, the statement misleadingly suggests that lindane scabies treatments are safe for use on children. To the contrary, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity" and that the products are "contraindicated in premature infants and individuals with known uncontrolled seizure disorders." The package insert accompanying Lindane Shampoo states: "Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane." The insert further warns: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." Moreover, the FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated

that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." That Advisory further warns: "Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes." The FDA Talk Paper announcing the black box states: The new boxed warning also states that Lindane Lotion and Lindane Shampoo are to be used with caution in patients who weigh less that approximately 110 pounds (50 kilograms). These products are not recommended for use in infants, and are contraindicated in premature infants. These warnings are based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients." The Centers for Disease Control and Prevention states that lindane products "should not be used to treat" children for head lice.

Second, by comparing a lindane product to an unapproved scabies treatment, the statement misleadingly suggests that lindane products are more effective than they are. Ivermectin, a drug used to treat worms in some animals as well as river blindness in humans, is an oral medication that is not an FDA-approved scabies treatment. Although there is some evidence that suggests ivermectin can be effective against scabies, those claims have not been fully evaluated by the FDA, and ivermectin for scabies remains an off-label use of the drug. As a result, there is little data about the efficacy of ivermectin as a scabies treatment option.

Therefore, calling ivermectin "one of the most potent medications on the market" and saying it failed while a lindane product worked misleadingly overstates the efficacy of lindane products.

Third, by stating that a lindane product worked where another product failed, this statement misleadingly implies that lindane products will always work where other products have failed or that lindane products are more effective than other treatment options. To the contrary, lindane treatments have been proven to be no more effective than other options. The FDA did not classify lindane products as last-resort or second-line options because they are more effective. Rather, the 1996 FDA Talk Paper makes clear that safety concerns and concerns about the high potential for misuse of lindane products prompted that decision. Given resistance of lice and scabies to other chemical treatment options and the fact that no product is 100% ovicidal, there are instances where lindane products will work where another product has failed. However, that happenstance does not mean lindane products are more effective than other chemical treatment options, and manual nit removal is still required because lindane products are not 100% ovicidal. Indeed, for lindane lice treatments, even as long ago as 1986, researchers recognized that "1% lindane shampoo, which is available only by prescription, offers no advantage in pediculicidal or ovicidal activity compared with several over-the-counter products." In 2002, researchers compared the efficacy of various chemical lice treatment options and concluded that Lindane Shampoo was the "slowest and least effective of all products tested," that "[l]indane resistance has been a worldwide problem for decades," and that "[i]n view of the extremely poor pediculicidal and ovicidal activity, potential toxic effects on the central nervous system, resistance, and environmental contamination, we find no reason for continued use of Lindane in the U.S. market . . . ." In addition, in passing its bill that banned lindane lice and scabies treatments in that state, the State of California concluded: "The State Department of

Health Services stated that Lindane is less effective and has more potential toxicity than the easily available alternatives; therefore, there is no reason to continue prescribing Lindane for the control of head lice in California."

Third, this statement misleadingly implies that lindane lice or scabies treatments are always safe to use after a person has already been exposed to another chemical treatment option. To the contrary, although the FDA has approved lindane products for use last-resort or second-line treatment options, the FDA has never fully evaluated safety considerations when a person applies first one pesticidal treatment and then follows that treatment with a lindane product.

Fourth, this statement and its placement on www.lindane.com and www.lindanetruth.com misleadingly or falsely suggest that lindane lice or scabies treatments are safe because an independent expert on par with the FDA believes them to be safe. This statement is posted on a portion of www.lindane.com and www.lindanetruth.com titled "Medical and Scientific Opinions," which consists of links to documents from several sources, including the FDA and the EPA. Labeling Dr. Hebert's statements a "Medical and Scientific Opinion[]" on par with statements made by the FDA and EPA misleadingly suggests that her statements about lindane products should be given the same weight as statements made by the FDA and EPA.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Dr. Adelaide Hebert. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(k) Statement listed in paragraph 74: "As the current President of the Society for Pediatric Dermatology, I can strongly attest to the value of Lindane for pediatric patients who suffer from scabies and lice. I have personally used this medication many times during my 21-year career in pediatric dermatology, and believe that it is both safe and effective when used according to the package insert."

First, this statement misleadingly suggests that lindane lice or scabies treatments are safely, appropriately, routinely, or typically used on children, who are the patients of pediatric dermatologists and the most likely to have problems with head lice. To the contrary, the FDA's mandated black box warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity" and that the products are "contraindicated in premature infants and individuals with known uncontrolled seizure disorders." The package insert accompanying Lindane Shampoo states: "Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane." The insert further warns: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver." Moreover, the FDA's 2003 Public Health Advisory states: "Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in

neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity." That Advisory further warns: "Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes." The FDA Talk Paper announcing the black box states: "The new boxed warning also states that Lindane Lotion and Lindane Shampoo are to be used with caution in patients who weigh less that approximately 110 pounds (50 kilograms). These products are not recommended for use in infants, and are contraindicated in premature infants. These warnings are based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients." The Centers for Disease Control and Prevention states that lindane products "should not be used to treat" children for head lice.

Second, this statement, in context with the previous statement identified in paragraph 73 of the Counterclaim, misleadingly implies that using a lindane product after ivermectin is use of a lindane product in accordance with FDA guidelines. To the contrary, because ivermectin is not approved to treat scabies, it is not a treatment option whose failure triggers a need for a lindane product as a last-resort treatment.

Third, this statement and its placement on www.lindane.com and www.lindanetruth.com misleadingly or falsely suggest that lindane lice or scabies treatments are safe because an independent expert on par with the FDA believes them to be safe. This statement is posted on a portion of www.lindane.com and www.lindanetruth.com titled "Medical and Scientific Opinions," which consists of links to documents from several sources, including the FDA and the EPA. Labeling Dr. Hebert's statements a "Medical and Scientific Opinion[]" on par with

statements made by the FDA and EPA misleadingly suggests that her statements about lindane products should be given the same weight as statements made by the FDA and EPA.

Individuals who have or may have knowledge or information about the misleading nature of this statement include: Deborah Altschuler and Dr. Adelaide Hebert. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(k) Statements listed in paragraphs 73 and 74: For the reasons explained above, the statements listed in paragraphs 73 and 74 of NPA's Counterclaim, and all found in the same letter posted on www.lindane.com and www.lindanetruth.com, create the overall misleading impression that (1) lindane lice or scabies treatments are safer or more effective than they really are; (2) that such products are safe for all patients, including children; and (3) that "experts" on par with the EPA and FDA believe lindane products are safe.

(l) Statement listed in paragraph 111: "[S]tatements against the use of lindane medication in favor of nit combs must be closely scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products."

This statement is both false and misleading.

First, the statement falsely implies that NPA is the only entity advocating against the use of lindane lice or scabies treatments. To the contrary, there are a number of organizations and individuals advocating against the use of lindane lice or scabies treatments. NPA's former co-defendant in this action, the Ecology Center, is one example. Other entities include, but are not

limited to, Pesticide Action Network North America, Alaska Community Action on Toxics, the Cancer Prevention Coalition, Consumers Union, Beyond Pesticides/National Coalition Against the Misuse of Pesticides, the Natural Resources Defense Council, the Michigan Network for Children's Environmental Health, and the Washington Toxics Coalition.

Second, the statement falsely implies that NPA is the only entity advocating the manual removal of lice and nits. To the contrary, there are a number of organizations that advocate safer treatment choices or non-chemical treatment choices, which include manual removal of lice and nits. Indeed, Dr. Tor Shwayder also has admitted that manual removal is one non-chemical option to manage head lice. In addition, FDA guidelines and other guidelines, such as those of the American Academy of Pediatrics, state that the use of nit combs is an important part of any lice management program, in that nit combs should be used to remove nits even after a pediculicide is used, and nit combs also can be used to detect or screen for lice infestations.

Third, the statement falsely categorizes NPA as a "special interest group." NPA is not a "special interest group"; rather, NPA is a non-profit educational organization. It hosts a website, www.headlice.org, as a repository for lice-related information, which includes lindane-related information, but it does not hire lobbyists to advocate its positions, and it engages in very little legislative advocacy work. Instead, NPA's work has focused on counseling those who contact NPA, ensuring that lice treatment is considered an important public health issue, providing education about lice and lice treatment, and protecting children from the misuse and abuse of lice and scabies treatments.

Fourth, the statement falsely implies that NPA advocates a non-chemical approach rather than lindane lice or scabies treatments in order to increase its profits. To the contrary, NPA advocated thorough lice and nit removal and careful screening and detection long before it

developed the LiceMeister® Comb because it believes that given the high potential for misuse of any pediculicide, combined with documented resistance to such chemicals and the fact that no chemical product is 100% ovicidal, manual removal is the safest option. Manual removal of nits is also the key to preventing misuse because of a continued infestation, since chemical options do not kill all nits. In addition, NPA developed the LiceMeister® Comb because other nit combs then on the market, usually sold alongside over-the-counter pediculicides, were ineffective. Other entities followed NPA's lead and developed other effective nit combs; now, parents and others have several effective options to choose from. Moreover, NPA's evidence, including its communications with parents and others who have used the LiceMeister® Comb, indicates that manual removal is an effective way to manage head lice. A December 2007 study further demonstrates the efficacy of the LiceMeister® Comb as a method for removing lice and nits. Indeed, Dr. Tor Shwayder also has admitted that manual removal is one non-chemical option to manage head lice. Finally, the LiceMeister® Comb is an effective medical device for screening and detecting head lice infestations, as indicated in particular by the fact that researchers have used the LiceMeister® Comb for this purpose to determine the efficacy of current or experimental lice treatment options.

Fifth, the statement falsely implies that NPA is a for-profit organization. To the contrary, throughout its 25-year history, NPA has been recognized by the federal government and the Commonwealth of Massachusetts as a valid nonprofit, charitable, or 501(c)(3) organization.

Sixth, the statement falsely states that NPA is a "group of non-healthcare professionals." To the contrary, NPA has relied and continues to rely on a variety of healthcare professionals who were or are formal or informal advisors. These individuals have been identified by NPA in its Rule 26(a)(1) initial disclosures and in other interrogatory responses. In addition, this

statement ignores the wealth of information NPA has acquired throughout its 25-year history working on lice and lice treatment issues.

Individuals who have or may have knowledge or information about the misleading nature of this statement include Deborah Altschuler. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(m) Statement listed in paragraph 113: The "[m]isleading [c]laim" that "[m]anual removal of lice and nits with special combs or other mechanical means is the best treatment for infestation and prevention of recurrence" is "often made by the National Pediculosis Association (NPA), which holds itself out as a nonprofit health organization but actually makes its money by marketing a competitive medical device to lindane shampoo without employing a single licensed healthcare professional."

This statement is both false and misleading.

First, the statement falsely implies that NPA is the only entity advocating against the use of lindane lice or scabies treatments. To the contrary, there are a number of organizations and individuals advocating against the use of lindane lice or scabies treatments. NPA's former co-defendant in this action, the Ecology Center, is one example. Other entities include Pesticide Action Network North America, Alaska Community Action on Toxics, the Cancer Prevention Coalition, and Consumers Union.

Second, the statement falsely implies that NPA is the only entity advocating the manual removal of lice and nits. To the contrary, there are a number of organizations that advocate safer

treatment choices or non-chemical treatment choices, which include manual removal of lice and nits. Indeed, Dr. Tor Shwayder also has admitted that manual removal is one non-chemical option to manage head lice. In addition, FDA guidelines and other guidelines, such as those of the American Academy of Pediatrics, state that the use of nit combs is an important part of any lice management program, in that nit combs should be used to remove nits even after a pediculicide is used, and nit combs also can be used to detect or screen for lice infestations.

Third, the statement falsely implies that NPA advocates a non-chemical approach rather than lindane lice or scabies treatments in order to increase its profits. To the contrary, NPA advocated thorough lice and nit removal and careful screening and detection long before it developed the LiceMeister® Comb because it believes that given the high potential for misuse of any pediculicide, combined with documented resistance to such chemicals and the fact that no chemical product is 100% ovicidal, manual removal is the safest option. Manual removal of nits is also the key to preventing misuse because of a continued infestation, since chemical options do not kill all nits. In addition, NPA developed the LiceMeister® Comb because other nit combs then on the market, usually sold alongside over-the-counter pediculicides, were ineffective. Other entities followed NPA's lead and developed other effective nit combs; now, parents and others have several effective options to choose from. Moreover, NPA's evidence, including its communications with parents and others who have used the LiceMeister® Comb, indicates that manual removal is an effective way to manage head lice. A December 2007 study further demonstrates the efficacy of the LiceMeister ® Comb as a method for removing lice and nits. Indeed, Dr. Tor Shwayder also has admitted that manual removal is one non-chemical option to manage head lice. Finally, the LiceMeister® Comb is an effective medical device for screening and detecting head lice infestations, as indicated in particular by the fact that researchers have

used the LiceMeister® Comb for this purpose to determine the efficacy of current or experimental lice treatment options.

Fourth, the statement falsely implies that NPA is a for-profit organization. To the contrary, throughout its 25-year history, NPA has been recognized by the federal government and the Commonwealth of Massachusetts as a valid nonprofit, charitable, or 501(c)(3) organization.

Fifth, the statement misleadingly implies that NPA must "employ[] a . . . licensed healthcare professional" in order to be a reputable source of information regarding lice treatments. NPA does not need to "employ" healthcare professionals to provide accurate information about head lice and related issues. Instead of paid employees, NPA has relied and continues to rely on a variety of volunteer healthcare professionals who were or are formal or informal advisors. These individuals have been identified by NPA in its Rule 26(a)(1) initial disclosures and in other interrogatory responses. In addition, this statement ignores the wealth of information NPA has acquired throughout its 25-year history working on lice and lice treatment issues.

Individuals who have or may have knowledge or information about the misleading nature of this statement include Deborah Altschuler. NPA believes that numerous other individuals have knowledge of the misleading nature of this statement, but to identify all such individuals is unduly burdensome, particularly when Morton Grove is in as good or better position to identify many of these individuals, such as its current or former employees. NPA further states that its investigation continues.

(n) Statements listed in paragraphs 63, 68-70, 73-74, 111, and 113: For the reasons explained above, the statements listed in paragraphs 63, 68-70, 73-74, 111, and 113 of

NPA's Counterclaim, and all found on www.lindane.com and www.lindanetruth.com, create the overall misleading impression that (1) lindane lice or scabies treatments are safer or more effective than they really are; (2) that such products are safe for all patients, including pregnant woman and children; (3) that lindane products are dangerous only if misused and safe if used according to directions; (4) that independent experts or "experts" on par with the EPA and FDA believe lindane products are safe; (5) that the NPA advocates against the use of lindane products in order to increase its profits; and (6) that manual removal of lice and nits and/or the NPA's LiceMeister® Comb are ineffective to manage head lice.

3. Identify every way in which the NPA has been harmed by/suffered damages as a result of the statements attributed to Morton Grove in the Counterclaim. In so doing, please state all specific facts upon which you base your allegations of harm/damages, identify all persons with knowledge or information regarding your allegations of harm/damages, and identify by Bates Numbers any and all documents relating to or reflecting such harm/damages.

RESPONSE: In addition to and without waiving the General Objections, NPA objects to this interrogatory because "the statements attributed to Morton Grove in the Counterclaim" is vague and ambiguous. NPA further objects to this interrogatory as overly broad and unduly burdensome because it requires NPA to identify each and every fact demonstrating how NPA has been harmed or is likely to be harmed by the false or misleading nature of the Morton Grove statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113. NPA also objects to this interrogatory as overly broad and unduly burdensome because it requires identification of "all persons with knowledge or information regarding your allegations of harm/damages," which category includes individuals, such as NPA's counsel, who have acquired knowledge by virtue of their participation in this case. NPA objects to this interrogatory as assuming facts not in evidence and as contrary to NPA's allegations in its Counterclaim because NPA is not claiming "damages" from Morton Grove; rather, NPA is seeking injunctive relief. NPA objects to this interrogatory because it contains discrete subparts that are properly the subject of separate

interrogatories. NPA also objects to this interrogatory to the extent it is duplicative of other interrogatories, namely, Interrogatory No. 1 of Morton Grove's Fourth Set of Interrogatories, to which NPA is responding herewith. NPA further objects to this interrogatory to the extent it seeks to impose obligations on NPA that are different from or more extensive than those imposed by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the Northern District of Illinois. NPA also objects to this interrogatory to the extent it requires NPA to identify documents not yet produced in this litigation or that are in Morton Grove's files and thus readily available to Morton Grove. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows:

NPA has experienced and continues to experience the following types of harm as a result of the false or misleading Morton Grove statements alleged in NPA's counterclaim.

First, NPA has experienced and continues to experience harm to its reputation and goodwill as a result of Morton Grove's statements. Specifically, Morton Grove's statements attempt to discredit NPA as a reputable source of information about lice-related issues, including treatment options, which has the effect of undermining NPA's ability to accomplish its mission to educate the public and protect children from the misuse and abuse of lice and scabies treatments. By calling NPA a "special interest group" and implying that NPA takes its positions only to increase its profits, Morton Grove has irreparably damaged NPA's credibility and prominence as the only independent non-profit organization in the United States that focuses on head lice and scabies issues. NPA's ability to fulfill its mission as a non-profit educational organization depends on its credibility and reputation, which it built over a 25-year history, as an organization that has accurate and helpful information on head lice issues. Morton Grove's false and misleading statements, and its accusation that NPA makes "[m]isleading claim[s]" about

manual removal, have tarnished that reputation and decreased NPA's ability to educate the public about head lice issues.

Second, as a result of the Morton Grove statements identified in paragraphs 111 and 113 of NPA's counterclaim, consumer perception of NPA's LiceMeister® Comb has been tarnished and will continue to be tarnished. Specifically, by implying that there is no basis for using a nit comb other than for NPA to push a special interest, anti-lindane agenda, Morton Grove has damaged the perception of the LiceMeister® Comb as a medical device effective to manually remove lice and nits. Moreover, by implying the LiceMeister® Comb is ineffective, Morton Grove also calls into question the usefulness of the LiceMeister® Comb to do things chemical treatments cannot – specifically, to screen and detect for head lice infestations, and to remove nits left over after any chemical treatment.

Third, if the Court concludes that NPA and Morton Grove are competitors, then NPA has suffered or will suffer competitive injury as a result of Morton Grove's false or misleading statements. NPA denies that its product, the LiceMeister® Comb, competes with Lindane Lotion and/or Lindane Shampoo. Nevertheless, should the Court determine that NPA and Morton Grove are competitors, the false and misleading promotion of Morton Grove's lindane products has increased or will increase Morton Grove's sales to the detriment of NPA's sales of its LiceMeister® Comb.

Documents relating to the harm NPA has or is likely to experience include, but are not limited to, documents relating to NPA's financial condition and documents showing the Morton Grove statements at issue. *See, e.g.*, NPA 03226-33; NPA 87423; NPA 86309-35; NPA 86382-402; MGP 001035-68. To identify all related documents is unduly burdensome.

Deborah Altschuler has knowledge of how NPA has been harmed or is likely to be harmed as a result of Morton Grove's false and misleading statements.

NPA further states that its investigation continues.

Dated: August 4, 2008

Respectfully Submitted,

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

By: _____
One of Its Attorneys

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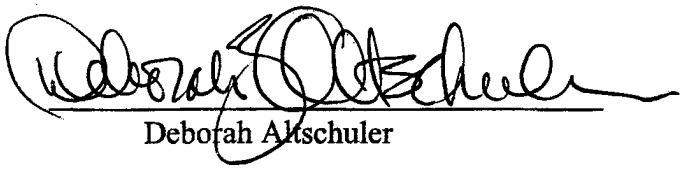
VERIFICATION

I, Deborah Altschuler, on behalf of The National Pediculosis Association, Inc., having read the foregoing Defendant The National Pediculosis Association, Inc.'s Responses to Plaintiff's Fourth Set of Interrogatories, declare under penalty of perjury that the statements made therein are true and correct to the best of my knowledge, information, and belief.



Deborah Altschuler

CERTIFICATE OF SERVICE

I, the undersigned, an attorney, hereby certify that on this 4th day of August, 2008, I caused a copy of **DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S RESPONSE TO PLAINTIFF'S FOURTH SET OF INTERROGATORIES** to be served by email and U.S. Mail, postage pre-paid, upon the following:

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Winston & Strawn LLP
35 W. Wacker Drive
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